(21) Application No. 19113/77

(22) Filed 6 May 1977

(23) Complete Specification filed 26 April 1978

(44) Complete Specification published 21 Jan. 1981

(51) INT. CL.³ A61M 16/00

(52) Index at acceptance
A5T ED

(72) Inventor LAWRENCE ALFRED COX

(54) LUNG VENTILATORS

(71) We, THE MEDISHIELD CORPORATION LIMITED, an English company, of Hammersmith House, London W6 9DX, England, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to lung ventilators, particularly to those used for intensive care, during which the patent is often incapable

of breathing voluntarily.

When a patient is recovering, it is important to 'wean' him from complete dependence on the ventilator. To effect this, ideally the ventilator should be capable of being operated in a mode in which spontaneous breathing (or ventilation) of a patient is both enabled and encouraged, while his ventilation performance is continually monitored against chosen standards so that the ventilator will revert automatically into its automatic mode should the patient's ventilation deteriorate to an unacceptable extent.

Methods used hitherto do not satisfy this requirement, as the monitoring function has to be carried out concurrently with manual adjustments to the ventilator's controls. Methods have been used in the past whereby the patient's end-tidal carbon dioxide level is monitored and made to adjust the inspired tidal volume automatically but these methods are both complicated and very expensive. Furthermore they have not so far been developed to the point of reliability or of satisfying the clinical requirements for weaning patients.

The present invention aims at providing a lung ventilator in which the minute volume of the exhaled gases is continuously monitored so that whenever a patient ceases to exhale sufficient gas per minute the ventilator automatically takes over from the patient.

Accordingly the present invention provides a lung ventilator comprising: a conduit through which pass the gases exhaled by a patient during the exhalation phase of each respiratory cycle; means adapted to produce a signal representing the rate of flow of gas passing through said conduit during each exhalation phase; means adapted to produce a signal representing the mean flow or volume exhaled per minute through said conduit; and means responsive to said signals for triggering the start of an automatic ventilation cycle when the mean flow or volume exhaled per minute is below a chosen threshold, and the rate of flow of the exhaled gases from the previous exhalation has virtually decreased to zero.

(19)

The invention will now be more particularly described, by way of example, with reference to the accompanying drawing, which is a schematic block diagram of a preferred embodiment of ventilator accord-

ing to the invention.

The ventilator is adapted to have respirable gases fed to it from a cylinder 2 or other suitable source. The gases are supplied at high pressure, and this is reduced to an intermediate pressure by means of a pressure regulator 4. Downstream of the regulator the inspiratory limb of the ventilator splits into two parallel flowpaths 5 and 7 controlled respectively by a demand valve 6 and a gate valve 8. The gate valve 8 is a controlled on-off valve, and the gases which flow through it when it is open have their rate of flow controlled by a regulator 16. The gases which issue from the regulator pass to a flow monitor 18 which is adapted to produce an electrical pulse for each unit volume of gas which passes through the monitor. These pulses are summated and used to drive a tidal volume meter 20.

Downstream of flow monitor 18 the flow-path 7 rejoins flowpath 5 in an outlet conduit 10 which is normally connected to a patient's breathing mask 12 through a length of flexible conduit 14. The mask 12 is designed to enable gases under pressure to be passed into the patient's lungs during the inhalation phase of the respiratory cycle, and to pass back to the ventilator, through a second length of flexible conduit 15 all the gases exhaled by the patient during the exhalation phase. Conduit 15 communicates

50

55

60

65

70

75

80

85

90

95

20

with the inlet side of a second flow monitor 24 from which the exhaled gases pass to an exhalation valve 26, the outlet of which is

connected to the atmosphere.

Similarly to monitor 18, monitor 24 provides a series of pulses of which each represents a unit volume of gases exhaled by the patient. These are fed both to a flow inhibitor 30, of which the function will be described below, and to an integrator 28. The pulses are continuously integrated at 28 and the integrated value displayed on a meter 29 in terms of minute volume. The integrated signal is fed also to a threshold control 32. Similarly to gate valve 8, exhalation valve 26 is a controlled on-off valve, and normally the valves 8 and 26 are controlled alternatively, so that if one is open the other is closed, and conversely.

The threshold control 32 is connected to a frequency override 34 and to a frequency timer 36 having as a second input a signal from flow inhibitor 30. A first output from timer 36 is to a frequency meter 38, while a second is to an I/E timer 40, which is effective to control the relative lengths of the inhalation (I) and the exhalation (E) phases of the respiratory cycle. The timer 40 is connected to a meter 42 displaying the current

effective I/E ratio.

When a patient is being weaned from the ventilator, the threshold control 32 is set manually to a value corresponding with a desired minimum minute volume for the patient who is connected to the ventilator

at the time in question.

When the patient is breathing normally, his attempts to inhale are detected by the demand valve 6, which opens to permit fresh respirable gas to by-pass the flowpath 7 and go directly to the patient's lungs. Each time the patient exhales, the gas passes through conduit 15, monitor 24 and valve 26 before being exhausted to the atmosphere. The ventilator is continuously integrating the exhalation phase to measure the minute volume, and effectively comparing it with the chosen minimum value. As long as the sensed minute volume exceeds the chosen minimum, the timer 36 is inhibited, and the apparatus will not cycle but permit the patient to breathe spontaneously. However, should the patient cease to breathe adequately, this is detected by the integrated signal of monitor 24 indicating that the respective minute volume is below the chosen minimum set by the threshold control 32. As soon as this happens, the frequency override 34 is actuated to enable the timer to switch on. This supplies an output signal to timer 40 which is immediately effective to open gate valve 8 and close exhalation valve 26, thus automatically initiating an inhalation phase. At the end of a period dictated by timer 40, the gate valve 8 is

closed and the exhalation valve 26 opened, to permit the patient to exhale. These conditions remain for a time dictated by timer 40 in order to preserve the chosen I/E ratio. At the end of this time, a fresh pulse from timer 36 is effective to initiate another cycle (provided that frequency override 34 has not since been actuated to inhibit the timer again). Thus timer 36 can be regarded as controlling the frequency with which the gate valve 8 is opened, while timer 40 controls the length of time for which the gate valve 8 remains open during the respective

respiratory cycle.

At the end of the time interval determined by the setting of the timer 36, when the ventilator would normally be switched into the inspiration mode, the patient may still be exhaling. This may be due to the patient suffering from an obstructed lung and/or because the I/E ratio has been set too short, giving insufficient time for the patient's pre-vious exhalation to be complete. In that event, the flow monitor 24 will sense that gas is still being exhaled, and the flow inhibitor 30 will inhibit timer 36 and prevent it from switching the ventilator into the inspiration mode. When the exhaled flow has dropped to a very low level the inhibit signal is removed, and the timer 36 is

allowed to switch on.

Following a change over from spontaneous breathing to automatic ventilation as described above the desired minute volume will, of course, be reestablished and when this 100 has been sensed by the threshold control 32 the frequency override 34 will once more be actuated to inhibit timer 36 and terminate automatic ventilation at the end of the respiratory cycle taking place. If the patient 105 meanwhile has not recovered his spontaneous breathing ability the process will be repeated. Because the threshold control 32 acts upon a signal derived from the continuous integration of the patient's exhaled flowrate there 110 will inevitably be a few seconds delay between his actual minute volume dropping below the threshold value and the initiation of automatic ventilation, and between the minute volume rising above the threshold 115 value and the termination of automatic ventilation. The degree of hysteresis effectively imparted to the system by the integrator is of value in preventing instability at the switching point between the 'spontaneous' 120 and 'automatic' modes of operation, while the delay in response to an inadequate minute volume is clearly insufficient to endanger the patient.

In practice the threshold control 32 may 125 be incorporated in the minute volume meter 29. Thus the meter may comprise a conventional moving-pointer analogue microammeter calibrated in volume units, the threshold control including an adjustable pointer 130

85

90

95

40

55

60

65

80

90

100

which can be set to any desired position on the meter scale. The adjustable pointer is fitted with a photocell sensor which triggers the frequency override 34 to initiate timer 36 and actuates an audio/visual alarm, in the event that the meter pointer indicating minute volume falls below the level to which the adjustable pointer is set. When the sensed minute volume subsequently increases and the moving pointer moves up the scale once more its passage past the adjustable pointer is again detected by the photocell and the timer is inhibited and the alarm(s) cancelled in response. A second adjustable pointer may also be provided, which is set to trigger an alarm in the event of an abnormally high minute volume being indicated by the meter 29.

Lung ventilators are known which have a so-called intermittent mandatory ventilation (IMV) mode. By this is meant that the ventilator can be set to go through an automatic ventilation cycle at intervals chosen by the operator irrespective of the adequacy of the patient's spontaneous breathing attempts. These 'intermittent' cycles reassure the patient that the ventilator is able to take over responsibility for ventilation should the patient's attempts to breathe become inadequate at any time. The ventilator of the present invention may be designed to have an IMV mode, as it can complement the exhalation volume triggered mode of the invention. In the case of the illustrated embodiment this may be achieved by the inclusion of a control 44 to actuate frequency override 34 and initiate the timer 36 at the chosen intervals.

WHAT WE CLAIM IS:-

1. A lung ventilator comprising: an exhalation conduit through which pass the gases exhaled by a patient during the exhalation phase of each respiratory cycle; means adapted to produce a first signal representing the rate of flow of gas passing through said conduit during each exhalation phase; means adapted to provide a second signal representing the mean flow or volume exhaled per minute through said conduit; and means responsive to said signals for triggering the start of an automatic ventila-

tion cycle when the mean flow or volume exhaled per minute is below a chosen threshold, and the rate of flow of the exhaled gases from the previous exhalation has virtually decreased to zero.

2. A lung ventilator according to claim 1 wherein the means adapted to produce said first signal comprise a flow monitor positioned in said conduit, and the means adapted to produce said second signal comprise means for integrating said first signal.

3. A lung ventilator according to claim 1 or claim 2 comprising: a timer for initiating and controlling the frequency of automatic ventilation; means responsive to said second signal for inhibiting said timer from initiating an automatic ventilation cycle when the mean flow or volume exhaled per minute is above the chosen threshold; and means responsive to said first signal for inhibiting said timer from initiating an automatic ventilation cycle before the rate of flow of the exhaled gases from the previous exhalation has virtually decreased to zero.

4. A lung ventilator according to any preceding claim comprising: an inlet for respirable gases; an outlet for passing such gases to a patient; a pair of gas flowpaths extending in parallel from said inlet to said outlet; a demand valve in a first of said flow paths to permit spontaneous breathing of the patient; an on-off valve in the second of said flow paths, the opening of which provides the inspiration phase of the automatic ventilation cycle; an on-off valve in said exhalation conduit; and means for controlling the operation of said on-off valves such that when one is opened the other is closed and conversely, and such that the valve in the exhalation conduit is closed only during the inspiration phase of the automatic ventilation cycle.

5. A lung ventilator according to any preceding claim further comprising means to effect intermittent mandatory ventilation.

6. A lung ventilator substantially as hereinbefore described with reference to the accompanying drawings.

> For the applicants: K. B. WEATHERALD, Chartered Patent Agent.

COMPLETE SPECIFICATION

1 SHEET

This drawing is a reproduction of the Original on a reduced scale

